

CLAIMS

What is claimed is:

1. A centrally maintained and managed information database system comprising:

data comprising at least one library of uniquely identifiable information for finished pharmaceutical dosage forms, said at least one library having uniquely identifiable information for finished pharmaceutical dosage forms manufactured by more than one manufacturer;

a central facility to house said data and to receive and/or transfer information to or from at least one user; and,

a communication link between said central facility and said user.
2. The information database system of claim 1 further comprising at least one satellite instrument at a local testing center remote from said central facility.
3. The information database system of claim 2 wherein the local testing center is located at a site in the supply chain of said pharmaceutical material.
4. The information database system of claim 3, wherein said site is selected from the group consisting of pharmaceutical manufacturers, drug distribution centers, drug repackaging facilities, ports-of-entry, customs facilities, import facilities, mail facilities, government centers, regulatory centers, pharmacies, hospitals, dispensaries, clinics, assisted-living facilities, and any combination thereof.

5. The information database system of claim 1, wherein said at least one library comprises data collected from forensic methods selected from the group consisting of near-infrared spectroscopy, infrared spectroscopy, UV-VIS spectroscopy, fluorescence spectroscopy, phosphorescence spectroscopy, Raman spectroscopy, microwave spectroscopy, photo-acoustic spectroscopy, X-ray spectroscopy, chemical imaging, and any combination thereof.
6. The information database of claim 1, wherein said at least one library comprises data selected from the group consisting of images of products, packaging attributes, labeling attributes, product codes, lot numbers, expiration dates, track and trace data, and any combination thereof.
7. The information database system of claim 1, wherein the communication link comprises an internet link.
8. The information database system of claim 1, wherein the database system further comprises a library of analytical information of known counterfeit finished pharmaceutical dosage forms.
9. The information database system of claim 1, wherein the pharmaceutical material comprises a finished pharmaceutical dosage form selected from the group consisting of oral dosage forms, injectables, inhalants, intravenous solutions, transdermals, suppositories, ophthalmics, and combinations thereof.
10. The information database system of claim 1, wherein said at least one library is a validated library.
11. The information database system of claim 1, wherein said at least one library is an updated library.
12. The information database system of claim 1, wherein the database system is a global database system.

13. The information database system of claim 1, wherein said database is maintained and managed by an entity distinct from said at least one user.
14. The information database system of claim 1, wherein said data comprising at least one library comprises a plurality of libraries.
15. The information database system of claim 1, wherein said central facility transfers data to said at least one user.
16. A centrally maintained and managed information database system comprising:
 - data comprising at least one library of uniquely identifiable information for pharmaceutical material selected from the group consisting of active pharmaceutical ingredients, excipients, pharmaceutical raw materials, pharmaceutical packaging materials, and combinations thereof, said pharmaceutical material manufactured by more than one manufacturer;
 - a central facility to house said data and to receive and/or transfer information to or from at least one user; and,
 - a communication link between said central facility and said user.
17. The information database system of claim 16, wherein said at least one library comprises data collected from forensic methods selected from the group consisting of near-infrared spectroscopy, infrared spectroscopy, UV-VIS spectroscopy, fluorescence spectroscopy, phosphorescence spectroscopy, Raman spectroscopy, microwave spectroscopy, photo-acoustic spectroscopy, X-ray spectroscopy, chemical imaging, and any combination thereof.

18. The information database of claim 16, wherein said at least one library comprises data selected from the group consisting of images of products, packaging attributes, labeling attributes, product codes, lot number, expiration dates, track and trace data, and any combination thereof.
19. The information database system of claim 16 further comprising at least one satellite instrument at a local testing center remote from said central facility wherein said local testing center is located at a site in the supply chain of said pharmaceutical material.
20. The information database system of claim 19, wherein said site is selected from the group consisting of pharmaceutical manufacturers, drug distribution centers, drug repackaging facilities, ports-of-entry, customs facilities, import facilities, mail facilities, government centers, regulatory centers, pharmacies, hospitals, dispensaries, clinics, assisted-living facilities, and any combination thereof.
21. The information database system of claim 16, wherein said at least one library is a validated library.
22. The information database system of claim 16, wherein said at least one library is an updated library.
23. The information database system of claim 16, wherein the database system is a global database system.
24. The information database system of claim 16, wherein said database is maintained and managed by an entity distinct from said at least one user.
25. The information database system of claim 16, wherein said data comprising at least one library comprises a plurality of libraries.

26. The information database system of claim 16, wherein said central facility transfers data to said at least one user.
27. A method for the determination of authenticity of a sample of pharmaceutical material comprising:
 - collecting data for said sample of pharmaceutical material at a remote location;
 - transmitting information to or receiving information from, a central facility having a database comprising data, said data comprising at least one library of uniquely identifiable information for authentic pharmaceutical material corresponding to said sample, said database comprising data for pharmaceutical material manufactured by multiple manufacturers; and,
 - comparing said data for said sample of pharmaceutical material to said data comprising at least one library.
28. The method of claim 27, further comprising the step of processing said data for said sample of pharmaceutical material.
29. The method of claim 27, wherein said at least one library is constructed from manufacturer-verified pharmaceutical material.
30. The method of claim 27, further comprising the step of supplementing the library with the analytical data collected for said sample at said remote location.
31. The method of claim 27, further comprising the step of collecting assay data relating to said sample.
32. The method of claim 27, wherein said sample comprises a pharmaceutical ingredient.

33. The method of claim 32 wherein said pharmaceutical ingredient comprises a pharmaceutical ingredient selected from the group consisting of active pharmaceutical ingredients, excipients, pharmaceutical raw materials, pharmaceutical mixtures, pharmaceutical packaging materials, and combinations thereof.
34. The method of claim 33 wherein said pharmaceutical ingredient is a pharmaceutical mixture.
35. The method of claim 34 wherein said pharmaceutical mixture is a granulation.
36. The method of claim 27, wherein said data comprising at least one library comprises data collected from forensic methods selected from the group consisting of near-infrared spectroscopy, infrared spectroscopy, UV-VIS spectroscopy, fluorescence spectroscopy, phosphorescence spectroscopy, Raman spectroscopy, microwave spectroscopy, photo-acoustic spectroscopy, X-ray spectroscopy, chemical imaging, and any combination thereof.
37. The method of claim 27, wherein said data comprising at least one library comprises data selected from the group consisting images of products, packaging attributes, labeling attributes, product codes, lot numbers, expiration dates track and trace data, and any combination thereof.
38. The method of claim 27, wherein said at least one library is a validated library.
39. The method of claim 27, wherein said at least one library is an updated library.
40. The method of claim 27, wherein said database is a global database.

41. The method of claim 27, wherein said database is maintained and managed by an entity other than that performing the step of collecting.
42. A method for the determination of authenticity of a sample of finished pharmaceutical dosage form comprising:
 - collecting data for said sample of finished pharmaceutical dosage form at a remote location;
 - transmitting information to or receiving information from, a central facility having a database comprising data, said data comprising at least one library of uniquely identifiable information for authentic finished pharmaceutical dosage form corresponding to said sample, said database comprising data for finished pharmaceutical dosage forms manufactured by multiple manufacturers; and,
 - comparing said data for said sample to said data comprising at least one library.
43. The method of claim 42, wherein said finished pharmaceutical dosage form is selected from the group consisting of oral dosage forms, injectables, inhalants, intravenous solutions, transdermals, suppositories, ophthalmics, and combinations thereof.
44. The method of claim 42, further comprising the step of processing said data for said finished pharmaceutical dosage form.
45. The method of claim 42, wherein said at least one library is constructed from manufacturer-verified pharmaceutical material.
46. The method of claim 42, wherein the method further comprises the step of supplementing the library with the analytical data collected for the sample at said remote location.

47. The method of claim 42, the method further comprises the step of collecting assay data relating to said sample.
48. The method of claim 42, wherein said data comprising at least one library comprises data collected from forensic methods selected from the group consisting of near-infrared spectroscopy, infrared spectroscopy, UV-VIS spectroscopy, fluorescence spectroscopy, phosphorescence spectroscopy, Raman spectroscopy, microwave spectroscopy, photo-acoustic spectroscopy, X-ray spectroscopy, chemical imaging, and any combination thereof.
49. The method of claim 42, wherein said data comprising at least one library comprises data selected from the group consisting of images of products, packaging attributes, labeling attributes, product codes, lot number, expiration dates track and trace data, and any combination thereof.
50. The method of claim 42, wherein said at least one library is a validated library.
51. The method of claim 42, wherein said at least one library is an updated library.
52. The method of claim 42, wherein said database is a global database.
53. The method of claim 42, wherein said database is maintained and managed by an entity other than that performing the step of collecting.
54. A method for the determination of authenticity of a sample of pharmaceutical material comprising:

collecting data for said sample of pharmaceutical material at a remote location;

transmitting to said remote location from a database at a central facility, data comprising at least one library of uniquely identifiable information for authentic pharmaceutical material corresponding to said sample, said database comprising data for pharmaceutical material manufactured by multiple manufacturers; and,

comparing, at said remote location, said data for said sample of pharmaceutical material to said data comprising at least one library.

55. The method of claim 54, wherein said database is maintained and managed by an entity other than that performing the step of collecting.

56. A method for the determination of authenticity of a sample of finished pharmaceutical dosage form comprising:

collecting data for said sample of finished pharmaceutical dosage form at a remote location;

transmitting to said remote location from a database at a central facility, data comprising at least one library of uniquely identifiable information for authentic finished pharmaceutical dosage form corresponding to said sample, said database comprising data for finished pharmaceutical dosage forms manufactured by multiple manufacturers; and,

comparing, at said remote location, said data for said sample to said data comprising at least one library.

57. The method of claim 56, wherein said database is maintained and managed by an entity other than that performing the step of collecting.

58. A method for the determination of authenticity of a sample of a finished pharmaceutical dosage form comprising:

collecting data for said finished pharmaceutical dosage form at a remote location;

transmitting information to or receiving information from, a central facility having a database comprising data, said data comprising at least one library of uniquely identifiable information for authentic finished pharmaceutical dosage form corresponding to said sample; and,

comparing said data for said finished pharmaceutical dosage form to said data comprising at least one library.

59. A pharmaceutical authenticity verification system comprising:

a centrally maintained and managed database having data comprising at least one library of uniquely identifiable information for pharmaceutical material,

a remote instrument, said remote instrument collects data for a pharmaceutical sample and is in communication with said database.

60. The pharmaceutical authenticity verification system of claim 59, wherein said database is maintained and managed by an entity other than the entity that collects said data for a pharmaceutical sample.

61. A computer-implemented method of verifying authenticity of a pharmaceutical sample, said method comprising:

providing a centrally maintained and managed database comprising data of at least one library of uniquely identifiable information for authentic pharmaceutical material;

comparing data collected from a pharmaceutical sample; and,
determining whether the pharmaceutical sample is authentic.

62. A product comprising a computer program on a computer readable memory executable by a computer, said program comprising:

instructions for receiving data for a pharmaceutical material,

instructions for comparing said data for a pharmaceutical material to data in a centrally maintained and managed pharmaceutical information database, and

instructions for determining whether said pharmaceutical material is authentic or counterfeit.

63. A centrally maintained and managed information database system comprising:

data comprising at least one library of spectroscopic information for finished pharmaceutical dosage forms, said dosage forms being manufactured by multiple manufacturers;

a central facility to house said library and to transfer information from said central facility to at least one user; and,

a communication link between said central facility and said user.

64. The centrally maintained and managed information database system of claim 63 wherein at least one library of spectroscopic information comprises Near-IR data, Raman data, chemical imaging data, and any combination thereof.

65. The centrally maintained and managed information database system of claim 64 wherein said database is maintained and managed by an entity other than said user.

66. A method to identify a counterfeit sample of pharmaceutical material comprising:

collecting data for a sample of pharmaceutical material at a remote location;

transmitting information to or receiving information from, a central facility, said central facility having a database comprising at least one library of uniquely identifiable information for pharmaceutical material, said uniquely identifiable information comprising data for pharmaceutical material manufactured by multiple manufacturers; and,

comparing said data for said sample to said at least one library.

67. The method of claim 66 wherein said pharmaceutical material comprises a pharmaceutical ingredient selected from the group consisting of active pharmaceutical ingredients, excipients, pharmaceutical raw materials, pharmaceutical mixtures, pharmaceutical packaging materials, and any combination thereof.
68. The method of claim 66, wherein said pharmaceutical material is a finished pharmaceutical dosage form selected from the group of consisting of oral dosage forms, injectables, inhalants, intravenous solutions, transdermals, suppositories, ophthalmics, and any combination thereof.
69. The method claim 66, wherein said database comprising at least one library comprises data for counterfeit pharmaceutical material.
70. The method of claim 69, further comprising the step of correlating said data for said pharmaceutical sample to complimentary data for said sample.
71. The method of claim 66, further comprising the step of processing said data for said sample.

72. The method of claim 66, wherein said at least one library is constructed from manufacturer-verified pharmaceutical material.
73. The method of claim 66, wherein the method further comprises the step of supplementing the at least one library with data collected for the sample at said remote location.
74. The method of claim 66, wherein said remote location is a site selected from the group consisting of pharmaceutical manufacturers, drug distribution centers, drug repackaging facilities, ports-of-entry, customs facilities, import facilities, mail facilities, government centers, regulatory centers, pharmacies, hospitals, dispensaries, clinics, assisted-living facilities, and any combination thereof.
75. The method of claim 66, further comprising the step of collecting assay data for said sample of pharmaceutical material.
76. The method of claim 66, wherein said database comprising at least one library comprises data collected from forensic methods selected from the group consisting of near-infrared spectroscopy, infrared spectroscopy, UV-VIS spectroscopy, fluorescence spectroscopy, phosphorescence spectroscopy, Raman spectroscopy, microwave spectroscopy, photo-acoustic spectroscopy, X-ray spectroscopy, chemical imaging, and any combination thereof.
77. The method of claim 66, wherein said database comprising at least one library comprises data selected from the group consisting of images of products, packaging attributes, labeling attributes, product codes, lot number, expiration dates track and trace data, and any combination thereof.
78. The method of claim 66, wherein said at least one library is a validated library.

79. The method of claim 66, wherein said at least one library is an updated library.
80. The method of claim 66, wherein said database is a global database.
81. The method of claim 66, wherein said database comprising at least one library comprises a plurality of libraries.
82. The method of claim 66, wherein said database is maintained and managed by an entity other than that performing the step of collecting data.
83. A method to detect a medication error comprising:
 - collecting data for a sample of finished pharmaceutical dosage form at a remote location;
 - transmitting information to or receiving information from, a central facility, said central facility having a database comprising at least one library of uniquely identifiable information comprising data for finished pharmaceutical dosage forms, and,
 - comparing said data for said sample to said at least one library.
84. The method of claim 83, wherein said finished pharmaceutical dosage form is selected from the group consisting of oral dosage forms, injectables, inhalants, intravenous solutions, transdermals, suppositories, ophthalmics, and any combination thereof.
85. The method claim 83, wherein said at least one library of uniquely identifiable information comprises data for counterfeit finished pharmaceutical dosage forms.

86. The method of claim 85, further comprising the step of correlating said data for said pharmaceutical sample to complimentary data for said sample.
87. The method of claim 83, further comprising the step of processing said data for said finished pharmaceutical dosage form.
88. The method of claim 83, wherein said at least one library is constructed from manufacturer-verified pharmaceutical material.
89. The method of claim 83, wherein the method further comprises the step of supplementing the library with the analytical data collected for the sample at said remote location.
90. The method of claim 83, wherein said remote location is a site selected from the group consisting of pharmacies, hospitals, dispensaries, clinics, assisted-living facilities, and any combination thereof.
91. The method of claim 83, the method further comprises the step of collecting assay data for said sample of finished pharmaceutical dosage form.
92. The method of claim 83, wherein said at least one library comprises data collected from forensic methods selected from the group consisting of near-infrared spectroscopy, infrared spectroscopy, UV-VIS spectroscopy, fluorescence spectroscopy, phosphorescence spectroscopy, Raman spectroscopy, microwave spectroscopy, photo-acoustic spectroscopy, X-ray spectroscopy, chemical imaging, and any combination thereof.
93. The method of claim 83, wherein said at least one library comprises data selected from the group consisting of images of products, packaging attributes, labeling attributes, product codes, lot number, expiration dates, track and trace data and any combination thereof.

94. The method of claim 83, wherein said at least one library is a validated library.
95. The method of claim 83, wherein said at least one library is an updated library.
96. The method of claim 83, wherein the database is a global database.
97. The method of claim 83, wherein said at database comprising at least one library comprises a plurality of libraries.
98. The method of claim 83, wherein said database is maintained and managed by an entity other than that performing the step of collecting data.